

Italy enacts new law on medically assisted reproduction

Andrea Boggio

Unité de recherche et d'enseignement en bioéthique, Centre Médical Universitaire, Université de Genève, 1211 Genève 4, Switzerland

E-mail: Andrea.Boggio@medicine.unige.ch

In 2004, the Italian Parliament enacted a law regulating medically assisted reproduction. Although the law recognizes as legal certain assisted reproduction techniques, several other procedures are implicitly or expressly banned: oocyte and sperm donation, using embryos for the scientific research purposes and reproductive cloning. In this article, I outline the new legal framework, pointing out some of the shortcomings of its provisions, such as the failure to define what an 'embryo' is, the contradictions between this law and the law on abortion, the opportunity for Italian couples to circumvent some of the prohibitions by resorting to 'reproductive tourism', and the central role that physicians play in the new legal framework.

Key words: cryopreservation/embryos (legal status of)/fertilization/medically assisted reproduction/preimplantation testing

Celestine Bohlen (1995) noted that 'Italy is virtually the only country in Europe that still has no law, no controls, not even any minimum regulations governing more than 100 private clinics that perform various fertilization procedures'. The legislative gap was eventually filled on February 19, 2004, when the Italian Parliament enacted Law 40/2004, which regulates medically assisted reproduction (MAR). Italian policymakers adopted a rather conservative stand, legalizing only few MAR techniques. This article analyses the recently enacted Law 40/2004 on MAR and the 2004 Ministry of Health Guidelines that integrate the legislation on the topic (Italian Ministry of Health, 2004). First, I outline the key points of the recently enacted provisions; second, I highlight some aspects that have characterized the political debate surrounding the Parliament's decision-making process.

MAR: admissible techniques

The new law regulates MAR techniques, which are ordinarily intended as all techniques that favour 'any form of non-coital conception' (Robertson, 1986). MAR techniques comprise 'all procedures that imply the transfer of human oocytes, sperm, and embryos for the purpose of inducing pregnancy' in the patient. The Ministry of Health Guidelines categorize MAR procedures into three levels based on complexity and invasiveness. In selecting the appropriate procedure, the treating physician gives priority to the technique that is the least complex and invasive according to the following Ministry categorizations:

- Level I: Intrauterine insemination, intraperitoneal insemination, Fallopian tube sperm perfusion (FSP) and ovulation induction;
- Level II: IVF, ICSI, percutaneous epididymal sperm aspiration (PESA), frozen testicular biopsy of gametes,

intra-Fallopian transfer of gametes (GIFT), zygotes (ZIFT) and embryos (TET);

- Level III: Micro-chirurgical testicular biopsy of gametes, and laparoscopies to transfer gametes, zygotes and embryos.

For each group of treatments, the Guidelines indicate the medical indications that suggest choosing a specific technique, and the technical and administrative procedures that physicians must follow in treating the couple.

Oocyte and sperm donation is forbidden. Consequently, couples who are unable to reproduce because one member of the couple is infertile may not seek donation. Critics of the 2004 legislation have pointed out that oocyte and sperm donations are legal in many European countries. In fact, France, Great Britain, Spain, Greece and Belgium allow oocyte and sperm donation. Consequently, Italian couples are able to seek treatments that are not allowed in Italy by travelling to other EU countries, circumventing the prohibition by resorting to so-called 'reproductive tourism' (Pennings, 2004). That European couples living in countries with more restrictive regulations have sought MAR treatments in more liberal countries has been documented (Baetens *et al.*, 2000; Vandervorst *et al.*, 2000; Pennings, 2001). It is very likely that the extremely restrictive Italian law will force couples increasingly to seek treatment for infertility in foreign countries. Although reproductive tourism may be seen as an opportunity to enjoy moral pluralism (Pennings, 2004), it raises domestic issues of inequality of access to health care, which is covered by public health insurance and thus accessible to all citizens. Besides the moral issue, reproductive tourism raises also constitutional issues. The constitutional rights to health care and to equal protection (Italian Constitution, 1947, Art.3 and 29) are jeopardized if access to some medical treatments for infertility depends upon the economic

means of infertile couples and their ability to secure those treatments in a foreign country.

Finally, surrogate motherhood is prohibited. Consequently, all surrogate mother contracts, which require the surrogate mother to consent to third party adoption of the child following birth and to facilitate the transfer of child custody, are null under the Italian Civil Code (1942, art.1325), because the law views them as being against public policy.

Cryopreservation and transfer of embryos

Cryopreservation of the sperm and oocytes is permissible if required by any of the procedures. On the other hand, the general rule is that cryopreservation of embryos is forbidden. In fact, 'no fertilization procedure can produce embryos in excess of three, and that all fertilized pre-embryos *must be implanted simultaneously*' (Law 40/2004, Art.14, sec.2, emphasis added).

The number of oocytes that can be fertilized is limited to three, and none of them can be transferred at a later time. Freezing embryos is therefore prohibited under normal circumstances, and if the first attempt to implant the fertilized embryos is unsuccessful, the patient will have to undertake a second hormone-based treatment to stimulate ovulation. If the first implantation fails, the mother-to-be may have to undertake repeated hormonal treatment and laparoscopies, thus imposing an undue burden on their health. Moreover, '[m]any centres report a reduction in the success rates for women aged >35 years and a steep increase in multiple pregnancies in those aged <35 years, who are often implanted with three embryos' (Turone, 2004).

Cryopreservation is allowed only under exceptional circumstances such as unforeseeable health conditions of the woman, making transfer of embryo(s) impossible. Thus, implantation may be delayed if the woman's severe and documented medical conditions could affect the outcome of the fertilization process. One can only speculate on which circumstances would justify a delay in the procedure. Italian policymakers clearly intended to permit deviations from the general rule—no general recourse to cryopreservation techniques—only under exceptional circumstances such as serious medical conditions that render physical transfer of the embryo impossible. A severe physical injury due to a car accident is likely to justify embryo cryopreservation.

In contrast with the principles of Law 40/2004 as enacted by the Parliament, the Ministry of Health Guidelines provide that the transfer of embryos cannot be imposed upon patients. This provision is in contrast with the rule imposing the transfer of all embryos unless the unforeseeable health conditions prevent a successful embryo transfer. However, the Guidelines prevent physicians from coercing women to be subject to non-voluntary implantations. This rule seems consistent with the voluntary nature of the procedure. Therefore, cryopreservation may be once again necessary as a practical matter. However, the legal framework does not regulate in detail when cryopreservation is required. The Guidelines simply state that the fertilized embryos must be cryopreserved for the shortest time possible and 'until its extinguishing' (Italian

Ministry of Health, 2004). The language is unclear and Italian policymakers must provide further guidance.

The Guidelines also provide for the frozen embryos that existed at the time the law was enacted. To deal with this issue, all institutions that produced embryos before February 2004 must advise the Ministry of Health of the number of embryos that had been produced and disclose the personal information of the couples who had resorted to MAR (Law 40/2004, Art.17, sec.2). Furthermore, the Guidelines distinguish between embryos that are likely to be implanted and 'abandoned' embryos, i.e. embryos that have not been claimed back by the requesting couple or that have been produced at the request of women who are not 'of potentially fertile age' (Italian Ministry of Health, 2004). While the same institutions shall keep those embryos that had been produced and that are likely to be implanted in the future, the Guidelines provide that 'abandoned' embryos will all be gathered in a central repository located in Milan. Governmental sources report that these embryos number 24 000 (De Bac, 2004).

Finally, it is noteworthy that both private and public hospitals may treat couples. As a general principle, if the treatment occurs in a public hospital, the national health care system bears the costs relating to the treatment. Both private and public fertility clinics may treat infertile patients only if listed in an *ad hoc* registry compiled by the Ministry of Health. This branch of the Italian Government may thus authorize institutions interested in performing MAR and monitor their operations after the authorization occurs.

Preimplantation testing

Preimplantation genetic testing is permissible; however, the law forbids selecting the embryos to be implanted or 'altering the genetic patrimony of an embryo or a gamete', only allowing genetic counselling to couples if 'severe and irreversible abnormalities' are detected (Law 40/2004, Art.13, sec.3). Consequently, all embryos that survive the fertilization stage must be implanted (Law 40/2004, Art.14, sec.2).

This provision raises issues of health for both women and newborns. The limitations on preimplantation testing have rapidly reached Italian courts (Turone, 2004). In May 2004, a trial judge denied the request of a married couple in which the woman was the carrier of the thalassaemia gene to have the embryos-to-be-implanted tested for thalassaemia and to prevent implantations of the embryos that would eventually result positive. The judge reasoned that, under the circumstances, preimplantation testing would be equal to 'an abortion as procedure to select fetuses based on their health conditions ... [thus resulting in] a eugenic utilization of abortion, which the law [on abortion] expressly forbids' (Trial Court of Catania, 2004).

The law also presents a legal paradox. As a practical matter, under the current law, the treating physician is required to implant all embryos unless a therapeutic abortion is permissible. Under the rules governing therapeutic abortion (Law 22 May 1978, n.194, art.4, 6), which permit this kind of abortion if the pregnancy imposes a 'severe risk' on

the woman's health, the treating physician may avoid implanting the fertilized embryos in the woman's womb if the transfer imposes a 'severe risk' on her health. The health of the patient rather than the potential dysfunction of the embryo determines the physician's decision. Moreover, once informed of genetic disease that will potentially affect the newborn, the parents may choose to have an abortion after the implantation. The requirement to impose on all embryos a regime of legalized abortion is illogical from a policy and ethical perspective, and medically inefficient. One way around the legal paradox is offered by the fact that the law does not sanction women who refuse the transfer of embryos. As a practical matter, this gap gives women some discretion to decline the transfer of embryos who tested positively for genetic diseases (Flamigni, 2004).

Eligibility

Under Italian law, infertility is required to be treated. These techniques shall be used to solve 'reproductive problems caused by sterility or human infertility' (Law 40/2004, Art.1). The Ministry of Health Guidelines provide that, although distinguishable, in the end, sterility and infertility are synonyms, and that 'sterility' should be construed as 'the absence of conception after 12/24 months of regular, unprotected sexual intercourse, besides the cases of a known pathology' (Italian Ministry of Health, 2004). Moreover, MAR is accessible only if all alternative treatments for infertility are not effective, which is certified by the treating physician. Thus, infertile couples have access to MAR only if it is properly documented and certified by the treating physician that the causes of infertility may not be clinically removed (Italian Ministry of Health, 2004).

Heterosexual couples—whether married or living together—in which both persons are aged ≥ 18 years and of potentially fertile age have access to MAR treatment (Law 40/2004, Art.5). Homosexual couples, minors and singles, i.e. individuals who are not in a heterosexual relationship, cannot access MAR procedures. Also post-menopausal women cannot undergo MAR treatment. In fact, the Ministry of Health Guidelines require that embryos that have been produced at the request of women who are not 'of potentially fertile age' shall not be implanted but rather collected in a central repository (this provision will be discussed later) (Italian Ministry of Health, 2004). Finally, all couples who are not infertile but are carriers of genetic diseases may not access MAR. On the other hand, a couple in a *de facto* relationship qualifies for treatment. However, the Parliament avoids defining in detail what a *de facto* relationship is, specifying only that it occurs whenever a man and a woman live together.

Both parents-to-be must be alive at the time the treatment for MAR begins. However, if the man's death occurs between the time of fertilization and implantation, the process is not interrupted and all fertilized embryos must be transferred to the woman's womb.

The eligibility provisions raise several constitutional issues of inequality of access. Under the Italian Constitution, 'all

citizens have equal social dignity and are equal before the law, without distinction of sex, race, language, religion, political opinion, personal and social conditions.' (Italian Constitution, Art.3). Moreover, the Constitutional Court may declare the law unconstitutional as being against the freedom of reproduction (Italian Constitution, Art.2, 29 and 31) and the freedom of self-determination (Italian Constitution, Art.13) if the Court finds that the law unreasonably limits the possibility of determination in reproductive choices of people who are in a relationship but do not live together, to single women, homosexuals, carriers of genetic diseases, etc.

Legal status and rights of the newborn

The law provides the same rights to children who are born under MAR techniques as to children who are conceived naturally (Law 40/2004, Art.8). Interestingly, the law addresses illegal fertilizations, for instance if the conceiving woman receives an illegal oocyte donation. In this scenario, paternal rights belong to the mother's spouse rather than the natural father. Thus, the mother's spouse or partner who is the recipient of an illegal sperm or oocyte donation cannot exercise his right to refuse paternity, and the donor does not bear any legal relationship with the newborn and is neither entitled to paternal rights nor bears any obligation. Finally, contrary to the case of natural or sexual procreation, the mother cannot remain anonymous to the child.

Medical research on human embryos

Medical research on human embryos is forbidden (Law 40/2004, Art.13). In fact, Italian law prohibits any manipulation or usage of the early human embryo other than for the purpose of bringing about its implantation into the uterus of the woman who produced the oocyte. Therefore, in the absence of alternative procedures, clinical research may be conducted only in the interest of the health and development of the embryo and with therapeutic and diagnostic aims. In other words, research and experimentation on embryos is allowed only within the context of clinical treatments.

Reproductive cloning, i.e. a 'procedure aimed to obtain a human being from one cell, possibly identical, in terms of genetic patrimony, to a different human being whether dead or alive,' is forbidden (Law 40/2004, Art.10, sec.7). More specifically, the new regulations explicitly forbid:

- creating human embryos for the purpose of doing research or experimenting on them;
- all forms of eugenic selection, including procedures that would manipulate or somehow artificially alter the genetic patrimony or predetermine genetic traits of the embryo or gamete;
- cloning by transferring the nucleus, by early scission of the embryo or by ectogenesis; and,
- fertilizing a human embryo with the gamete of a living entity of a different species.

Unfortunately, neither the law nor Guidelines define 'embryo'. Contrary to Germany (Deutscher Bundestag, 1990)

and Switzerland (Assemblée fédérale de la Confédération suisse, 1998, Art.2), Italian lawmakers avoided taking a position on whether an 'embryo' exists from fertilization (sperm penetration into the oocyte) or syngamy (fusion of the maternal and paternal pronuclei). Although banning research on embryos, both the German and Swiss laws allow the cryopreservation of an oocyte after penetration by sperm but before a zygote is formed (ootid). Italian practitioners have already pointed out the problems left open by the normative gap. Recently, Carlo Flamigni, a medical expert in MAR techniques and a member of the National Bioethics Committee, announced his provocative intention to admit to the Bologna authorities that he froze an ootid. 'Maybe I'll be arrested ... but maybe the judge will decide that, according to the law, the ootid and even the zygote can be frozen, since neither was cited in the law', Flamigni added (Turone, 2004). From a practical point of view, the ambiguity of the legal notion of 'embryos' could be used to circumvent the ban on the selection of embryos to be implanted to the advantage of couples who carry genes for monogenic diseases. In fact, conducting genetic screening of the ootids before syngamy is not expressly outlawed. However, there is need for legal certainty in this area to provide clear guidance to practitioners on the delicate issues of whether individual human life begins with the formation of the unique genome after the diploid chromosome set has been formed from parental DNA.

The sanction for illegal reproductive cloning is jail time ranging from 10 to 20 years. Finally, all experiments on embryos, i.e. including genetic cloning, eugenic procedures, and mixing human genes with genes from other species are criminally punished under the new law.

The role of physicians and the patient/physicians relationship

Treating physicians play a substantial role in the recently enacted legal regime. First, treating physicians decide whether or not the requirements to access MAR techniques are met and which treatment better suits a couple's medical conditions. They also certify that the couple is a '*de facto*' couple, thus entitling them to being treated. Second, treating physicians shall provide counselling to the couple if abnormalities are detected in the preimplantation stage. Third, treating physicians can exercise some discretion in filling up all those legislative gaps that Italian policymakers have not addressed. In fact, treating physicians may test the ootids for monogenic diseases, inform the patients of the tests' outcomes, and, if the couples so wish, interrupt the treatment or favour the syngamy of the ootids that are not carriers of genetic diseases. The law assigns no role to Ethics Committees or similar institutional, advisory bodies that may facilitate physicians discharging their duties. On the other hand, treating physicians and the people who assist them in performing illegal procedures may be criminally and civilly sanctioned. In fact, violators may be punished with either monetary fines or, in fewer yet more substantial violations, incarceration. Among the criminally sanctioned procedures, the law lists

utilizing a gamete with the purpose of performing an illegal fertilization, marketing gametes, treating same-sex couples, single women, and couples in which at least one partner is a minor. Finally, treating couples without obtaining prior consent to the MAR in medical institutions that are not listed in the *ad hoc* registry compiled by the Ministry of Health is civilly and criminally punishable.

Both the mother-to-be and father-to-be must provide informed consent to the treatment in writing ≥ 7 days prior to beginning the fertilization process. Both may withdraw consent at a later time up until the oocyte is fertilized. Withdrawal of consent is thus time sensitive: once fertilization occurs, the process is irreversible. This provision has raised concerns among policymakers—mostly from the left-wing coalition—claiming that a lack of flexibility imposes a burdensome limitation on the woman's right to choose whether or not to have a pregnancy. In fact, although unexpected events such as the death of a partner may happen between the time of fertilization and implantation, they cannot stop the process, even if the woman has changed her mind and no longer wants to proceed with the treatment. The law punishes physicians who treat couples without obtaining their informed consent prior to treatment. Interestingly, the patients of illegal treatments are never punished under the law unless they engage in marketing oocytes, sperm or embryos, or participate in reproductive cloning.

Physicians and their assistants may object to MAR based on moral beliefs. In objecting, they must give notice of this to the medical institutions where they perform medical services. At any rate, they may revoke their statements of conscious objection at any time; however, their revocation will only be effective for 30 days after it is made.

The ethical and political debate

To many foreign observers, Italian politics are often unintelligible. The political debate surrounding the enactment of the new law regulating MAR is no exception to the general rule. The final text of the law was approved by the Parliament after lengthy discussion within the legislative arena and mass media. Over the years, different bills were proposed for approval, and the Parliament eventually approved a draft that combines some of the proposals. The government, led by Mr Berlusconi, was able to overcome the dichotomy within society on several ethical and social issues. In fact, the conservative majority was able to attract the votes of Parliament's Catholic members in enacting a conservative law on MAR and *in vitro* research on embryos. The vote on the MAR law united openly Catholic members of Parliament, creating what is called, in the jargon of Italian politics, a 'transversal party.' The Senate approved in second reading the final draft of the law with a majority of 169 members (92 members were opposed and five members abstained). The view of a 'transversal party' is generally supported by the consideration that many provisions are perfectly aligned with the view held by the Roman Catholic community and the Vatican in particular. The Vatican reportedly informally endorses the Italian Parliament's narrow legalization of

certain forms of MAR. Under the Vatican's view, IVF and reproductive cloning are both 'terrible aberrations to which value-free science is driven and is a sign of the profound malaise of our civilization, which looks to science, technology and the 'quality of life' as surrogates for the meaning of life and its salvation' (Pontificia Academia Pro Vita, 1997).

Moreover, the law is also the outcome of political bargaining between Catholics and the liberal members of Parliament who wanted certain forms of MAR, such as IVF and artificial insemination, legalized. In fact, the law affirms that medically assisted conception in itself is not unethical, but that certain forms must be prohibited. Procreation is thus moral even though disconnected with sexual activity, a principle in contrast with the teachings of the Roman Catholic Church. Furthermore, although denying singles and homosexual couples access to MAR techniques, the law does not limit access to IVF to married couples, recognizing *de facto* relationships.

It is also interesting to note the division between the members of the Italian National Bioethics Committee. The Committee Chairman and one of its Catholic members publicly endorsed the new regulations on several occasions. On the other hand, six Committee members—along with a group of intellectuals—signed a harsh letter expressing great concern about the recently enacted law. The signatories of the letter view the new regulations as 'a radical attack to civil growth in [Italy] ... [which] imposes bans and harsh limitations providing for sanctions often inspired by a senseless view of punishment'. Most of all, the letter argues that the law breaches the constitutional principle of separation between church and state—an argument often endorsed by other commentators in the public debate (Levi Montalcini *et al.*, 2003).

Conclusion

The new Italian law on MAR regulates a field of medical practice and research that has been non-regulated for years. The Parliament conservatively prohibits treatments such as oocyte donation and sperm donation that are legal in several other modern democracies. Furthermore, the law prohibits the more controversial reproductive cloning and research on embryos. The new provisions have raised, rather than solved, the debate over complex and difficult issues. In the coming months and years the medical community will implement those principles in its daily practice. It is very likely that some of the provisions will be circumvented in daily practice. If the effectiveness of the new law becomes an issue of implementation and of conscience for those physicians who are asked to make decisions in the isolation of their laboratories, the future of the law will be uncertain. In 2005, a public referendum on several key provisions of the law will likely take place. Although the Constitutional Court did not

admit that the referendum seeks the entire repeal of the MAR law, it admitted four referenda that seek to repeal: (i) the restrictions on embryonic stem cell research; (ii) the requirement not to fertilize more than three embryos per treatment; (iii) the requirement that embryo transfer must be mandatory; and finally (iv) the ban on oocyte and sperm donation. Perhaps the Constitutional Court's approval of the referendum on these four questions is a good opportunity for the Parliament to re-open the debate on solving some of the contradictions and gaps that this article has highlighted, and to accommodate more liberal views on this controversial yet crucial issue.

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